

### **REMARKS/ARGUMENTS**

Upon entry of this amendment, claims 1-9 and 17-52 are in this application. Claims 10-16, which were withdrawn as being directed to non-elected subject matter, have been cancelled, without prejudice. Claims 9-16 are cancelled. Claims 49 – 52 are added.

Claim 3 has been amended for purposes of clarity. New claim 49 is supported in the specification on page 36, line 18 and by original claim 3. New claims 50-52 are supported on page 17, lines 4-17. These amendments do not narrow the scope of the invention or the equivalents to which they are entitled. No new matter is added by this amendment.

Claims 1-9 and 17-48 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

Applicant respectfully requests reconsideration of this rejection.

The claims recite that the multifunctional molecular complex of the invention, which comprises two components: a nucleic acid composition and a transfer moiety, transfer the nucleic acid composition to a host cell.

The examiner argues that the application does not reasonably provide enablement to methods for the nuclear transfer of a nucleic acid composition to cells in vivo comprising introducing a multifunctional molecular complex to cells where the complex comprises a nucleic acid encoding a therapeutic protein or polypeptide and a transfer moiety. However, there is no requirement in either the specification or the claims that the transfer be to the nucleus of the cell. Applicant submits that the examiner has improperly rejected the claim on the basis of language which is not recited and which is not an element of the claims.

Applicant has generated data demonstrating that several multifunctional molecular complexes of the invention transferred a nucleic acid composition to a wide

variety of cell types. Attached is a copy of the Rule 131 Declaration presented by applicant in US Patent Application No. 08/809,397 - - which the instant examiner allowed and which has issued as US Patent No. 6,127,170 October 3, 2000. The examiner has stated that she "would agree that the claims are enabled for methods of transfer where the target cells are cultured cells". [It is noted that claim 4 recites that the target cells are cultured cells. Thus, at a minimum, claim 4 should be free of this rejection.]

The examiner fails to find the claimed methods to be enabled for methods of transfer where the target cells are contained with a body or *in vivo*. The examiner has stated that "the *in vivo* aspect of claims 1-9 and 17-48 are interpreted as gene therapy as the specification does not disclose a use for delivering a therapeutic protein other than for therapeutic purposes".

Applicant will agree that a therapeutic protein would be delivered for a therapeutic purpose. However, it must be noted by the examiner that the claims are not so limited. The claims recite "a nucleic acid composition" (claim 1), that "encodes a peptide or protein" or "serves as a template for a nucleic acid molecule" (claim 2).

While the specification recites that the encoded peptides or proteins can be therapeutic agents, the encoded peptides or proteins may also be vaccines, foodstuffs and nutritional supplements, compounds of agricultural significance, herbicides and plant growth regulants, insecticides, miticides, rodenticides, fungicides, compounds useful in animal health, parasiticides, and nematocides. Thus, the methods of the invention are also for transferring desirable nucleic acid compositions to plants and non-human animals for a variety of purposes unrelated to gene therapy. [Specification, page 13, lines 31-37, and claim 3.] Further, the nucleic acid compositions of the invention can be used to delivery nucleic acid molecules which serve as templates for antisense molecules and ribozymes [page 23, lines 10-13].

Further, Applicant has generated data demonstrating that an exemplary nucleic acid composition transferred by a multifunctional molecular complex of the invention

Application No. 10/010,114  
Amdt. dated March 5, 2004  
Reply to Office Action dated December 8, 2003

expressed a protein *in vivo* and induced immune responses thereto. See, attached above-identified Rule 131 Declaration.

The claims are drawn to methods of transferring (delivering) a nucleic acid composition to a host cell. Applicant submits that, having demonstrated that the method of the invention works in culture and *in vivo*, there is no basis for questioning enablement on the basis of the types of molecules encoded by the DNA molecules transferred.


Reconsideration and withdrawal of this rejection is requested.

Since, as noted by the examiner, the prior art does not teach or suggest methods of transfer using a transfer moiety of the claims, Applicant requests that the present application be permitted to pass to issue.

The Director of the US Patent and Trademark Office is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to Deposit Account No. 08-3040.

Respectfully submitted,

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